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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,693	DEUTSCH, HARVEY L.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *25-39,41,42,45-47 and 72-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,40,43,44 and 48-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/06/2007, 02/15/2007, 01/04/2007, 03/06/2007.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

a. Group I, claim(s) 1-24, 40, 44, 43 and 48-71, drawn to a drainage device comprising a first component, second component and elongated tubular mesh, and method of using.

b. Group II, claim(s) 25-39,41,42,45-47 and 72-91, drawn to another drainage device comprising a first component, second component and elongated tubular mesh, and another method of using.

The following claim(s) are generic: currently, no claims are generic.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. Where the group of inventions is claimed in one and the same international application, the requirement for unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions considered as a whole, makes over the prior art. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2, although they share the special technical feature, this special technical feature does not define a contribution over the prior art for the following reasons:

4. The common technical feature of a first component comprising a distal segment, where the distal segment comprises an elongated tubular mesh as claimed [claims 1 and 25], or a tubular mesh as claimed [claim 48] is known in the art. For example, Driskill (US Patent 6,517,551) discloses an intravascular foreign object retrieval catheter (cols. 3-4, lines 59-5), further comprising:

5. a first component comprising a distal segment (col. 5, lines 4-11, Fig. 1, second basket catheter 14 having distal segment);

6. where the distal segment comprises an elongated tubular mesh (col. 5, lines 20-24, Fig. 1, second basket catheter 14 connected to containment basket 30). The shared technical feature of an elongated tubular mesh does not provide a contribution over the prior art, and no single general inventive concept exists. Therefore the restriction is appropriate.

7. Claims 25-39, 41, 42, 45-47 and 72-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-24, 40, 44, 43 and 48-71 are examined on the merits. Applicant traversed the restriction (election) requirement in the reply filed on 01 May 2009. A petition to revive has been filed and acknowledged.

8. Applicant requests to clarify the language "election of species" used in the previous Office Action. Examiner notes that only a restriction requirement was applied, and Applicant has responded appropriately.

9. Applicant asserts that restriction to Groups I and II is inappropriate, since claim 25 is generic to at least most claims in Group I. Examiner notes that the restriction requirement is based on groups of claims sharing the same common technical feature, namely a tubular mesh. Driskill teaches that a tubular mesh for removing occlusions is known in the art, and therefore this limitation does not provide a special technical feature. The occlusion removing structure is common to the groups, but does not define a special technical feature.

10. The requirement is still deemed proper and is therefore made FINAL.

35 USC § 112, 6th Paragraph

11. With regard to Applicant's "means for drainage" and "means for removing an occlusion" of claim 43, the language appears to be an attempt to invoke 35 USC 112,

6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

12. Regarding claim 43, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification (p. 3, lines 19-21, p. 11-12, lines 26-3, means for removing an occlusion corresponding to a second component 14, and means for drainage corresponding to third component 16).

Claim Objections

13. Claims 22 and 40 are objected to because of the following informalities: claim 40 depends on claim 22, and repeats the same language. Examiner suggests canceling claim 40 since it adds no limitations to the claimed device. Appropriate correction is required.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 48 and 49 are rejected under 35 U.S.C. 102(a) as being anticipated by Ouriel, Kenneth et al. (US 20030097114).

16. Regarding claim claims 48 and 49, Ouriel discloses a kit for removing an occlusion from an occluded drain comprising:

[48] an introducer (¶ [0034], Figs. 3, 4, Figs. 3, 4, second catheter assembly 20); and

[48] an occlusion removing structure comprising a tubular mesh (¶ [0034], [0037], Figs. 3, 4, filter 76 forming filter basket 120);

[49] where the tubular mesh is preloaded into an introducer (¶ [0037], [0038], Figs 3, 4, filter 76 housed within sleeve 74). The limitation of "preloaded" does not add structure to the claimed device. Additionally, Ouriel discloses that filter 76 is already present within the catheter assembly when deployed to a vessel (¶ [0042], first and second catheter assemblies 20, 70 inserted into blood vessel 12).

Examiner notes that 35 USC § 112, 6th Paragraph is not invoked for claims 48 or 49. Therefore, surgical second catheter assembly 20 of Ouriel is interpreted as an introducer. Second catheter assembly 20 surrounds an occlusion removing structure, and introduces a catheter into a blood vessel.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 1-7, 9-13, 15-20, 43, 50-55, 57, 59-61, 64-66 and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magers; Paul E. et al. (US 3742952) in view of Ouriel, Kenneth et al. (US 20030097114).

20. Regarding claim 1, Magers discloses a drainage device for draining a space or cavity defined by a wall (col. 1, lines 1-16, col. 2, lines 58-68), the drainage device comprising:

a) a first component comprising:

a proximal segment (col. 2, lines 58-68, Fig. 1, surgical needle 15);

an intermediate segment (col. 2, lines 58-68, Fig. 1, right portion of drainage tube 13); and

where the intermediate segment and the distal segment function as an occlusion removing structure; and

b) a second component that functions as a drain (col. 2, lines 58-68, Fig. 1, left portion of drainage tube 13);

where the drainage device comprises a proximal end and a distal end (Fig. 1, left portion of drainage tube having proximal and distal ends);

where the proximal end of the proximal segment comprises an instrument for creating an opening in the wall of the space or cavity (col. 3, lines 41-54, Fig. 1, needle 15 having point at right end);

where the intermediate segment comprises a proximal end and a distal end (Fig. 1, right portion of drainage tube 13 having proximal and distal ends); and

further comprises a hollow tube comprising a wall with an outer surface and an inner surface defining a central lumen (Fig. 1, right portion of drainage tube 13 having wall, outer surface, inner surface and lumen);

where the second component comprises a proximal end-and a distal end (Fig. 1, left portion of drainage tube 13 having proximal and distal ends); and

further comprises a hollow tube comprising a wall with an outer surface and an inner surface defining a central lumen (Fig. 1, left portion of drainage tube 13 having wall, outer surface, inner surface and lumen);

where the first component further comprises a proximal-segment comprising a proximal end and a distal end (Fig. 1, needle 15 having proximal and distal ends); and

where the distal end of the proximal segment is connected to the proximal end of the intermediate segment (Fig. 1, needle 15 connected to proximal end of drainage tube 13).

Magers discloses the invention substantially as claimed, see above. However, Magers lacks a first component comprising a mesh distal segment, and non-integrally-connected first and second components as claimed [claim 1]. Ouriel discloses an apparatus and method for performing thrombolysis (¶ [0001], [0002], [0027], Figs. 1-7, apparatus 10), comprising:

a first component (Figs. 3, 4, combination of second catheter 72 and filter 76), comprising:

an intermediate segment (¶ [0034], Figs. 3, 4, second catheter 72); and

a distal segment (¶ [0034], [0037], Figs. 3, 4, filter 76 forming filter basket 120);

where the intermediate segment and the distal segment function as an occlusion removing structure (¶ [0044], [0045], Figs. 3, 4, filter basket 120 trapping fragments); and

a second component that functions as a fluid conductor (¶ [0030], [0044], Figs. 3, 4, first catheter 24 for infusing thrombolytic fluid);

where the first component and the second component are non-integrally-connected (¶ [0036], Figs. 3, 4, sleeve 74 between first catheter 24 and second catheter 72, therefore catheters 24 and 72 non-integrally-connected);

where the distal end of the intermediate segment is connected to the proximal end of the distal segment (Figs. 3, 4, connection between second catheter 72 and filter 76);

where the distal segment comprises an elongated tubular mesh comprising a proximal end, a distal end, an outer surface and an inner surface defining a central lumen (Figs. 3, 4, filter 76 comprising tubular mesh and comprising proximal and distal ends, outer and inner surfaces and central lumen).

Ouriel removes thromboses from an occluded vessel using a tubular mesh, and retracts the tubular mesh within a perforated lumen (Figs. 3, 4, first catheter 24 having infusion ports 42). One would be motivated to modify Magers with the tubular mesh as taught by Ouriel to remove blockage since the tubular mesh of Ouriel removes and filters thromboses from a lumen. Additionally, Magers calls for one-way fluid flow from a wound to a collection container (cols. 4-5, lines 22-26, 64-5 preventing fluid from returning to a wound). An occlusion-removing structure of Ouriel prevents fluid from

backing up into a wound, as would be caused by occlusions blocking the perforated portion of drainage tube 13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Magers as discussed with the tubular mesh as taught by Ouriel in order to prevent fluid from backing up in a wound.

21. Regarding claims 2-6 and 9-13, Magers discloses a drainage device where:

[2] the device comprises a trocar (col. 3, lines 41-54, Fig. 1, needle 15 passed through tissue and functioning as trocar);

[3] the instrument is bent or curved along its longitudinal axis (Fig. 1, needle 15 depicted as bent downwards);

[4] the distal end of the proximal segment comprises a first connector for joining the proximal segment to the intermediate segment (col. 2, lines 58-68, Fig. 1, barbed dull end 17);

[5, 6] where the inner surface of the wall of the hollow tube of the intermediate segment fits snugly over the distal end of the first connector of the proximal segment, to integrally join the proximal segment to the intermediate segment (Fig. 1, right end of drainage tube 13 fit over barbed dull end 17);

[9] where the proximal end of the distal segment is integrally joined to the distal end of the intermediate segment (Fig. 1, left and right sections of tube 13 integrally joined);

[10] where the hollow tube of the second component is flexible (col. 3, lines 41-54, perforated end of tube 13 drawn into the wound);

[11] where the hollow tube of the intermediate segment is flexible (col. 2, lines 58-68, col. 3, lines 41-54, Fig. 1, right end of drainage tube 13 alternately fit over barbed dull end 17 or inserted into bore 33 in plug body 30);

[12] where the-hollow tube of the second component further comprises a plurality of apertures extending completely through the wall of the hollow tube of the second component, from the outer surface of the hollow tube of the second component to the inner surface of the hollow tube of the second component (col. 2, lines 58-68, Fig. 1, perforated portion of tube 13);

[13] where the plurality of apertures are arranged in a plurality of rows (Fig. 1, perforations 12 depicted as a plurality of rows);

22. Regarding claim 43, Magers discloses a drainage device for draining a space or cavity defined by a wall, the drainage device comprising means for drainage (col. 2, lines 58-68, Fig. 1, left portion of drainage tube 13). Magers discloses the invention substantially as claimed, see discussion of claim 1 above. However, Magers lacks means for removing an occlusion as claimed [claim 43]. Examiner cites Ouriel as teaching a means for removing occlusions consistent with the disclosure in the specification as required by 35 USC § 112, 6th Paragraph (Ouriel, ¶ [0034], [0037], Figs. 3, 4, filter 76 forming filter basket 120). Regarding rationale and motivation to modify Magers in view of Ouriel, see discussion of claim 1 above.

23. Regarding claims 15-20, Magers in view of Ouriel discloses the invention substantially as claimed, including first and second components; see above. However, both Magers and Ouriel are silent regarding the distal segment axial length relative to

the second component axial length as claimed [claim 15-20]. Applicant claims relative lengths of between 60%, 70%, 80 %, 90%, 95% and 99 % to 100% of a distal segment to second component second component axial length. Examiner interprets the claimed relative lengths as a result-effective variable, subject to experimentation and testing. A result-effective variable is a parameter which achieves a recognized result. These results are obtained by the determination of optimum or workable ranges of said variable through routine experimentation. The property of relative lengths cleans blocked sections of a lumen selectively through routine experimentation. For example, Ouriel discloses a tubular mesh that expands radially (¶ [0034], [0037], Figs. 2, 3, expandable filter 76), and suggests varying the length of a second portion (¶ [0046], Fig. 6, changing length of infusion section 40 of first catheter 24). Here, Ouriel adjusts the relative lengths of a distal segment and second component in order to clean a lumen blocked by thrombosis (¶ [0044]).

Additionally, different wounds and different patients require different catheter sizes. Applicant discloses draining fluid from different regions in the body (specification, p. 1, line 10, drains for the back, breast, chest, head, hip and vertebral column). Surgical wounds in these areas require differently sized catheters. For example, an incision in the chest or abdomen for hernia repair will be longer than one in the back for a disc replacement.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the relative lengths of a distal segment and second component order to clean differently sized blockage, size a drainage device for

different sized wounds, or fit different patients. See MPEP 2144.05(II)(A,B). Also see in re Boesch and Slaney, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

24. Regarding claim 50, Magers discloses a method for draining a cavity or space with a drain, and unoccluding the drain, the method comprising:

a) selecting a space or cavity to be drained, where the space or cavity comprises a wall substantially defining the space or cavity to be drained (col. 3, lines 41-54, selecting wound cavity);

b) providing a drainage device according to claim 1 (see discussion of claim 1 above);

c) placing the distal end of the drainage device within the space or cavity to be drained through a first opening (col. 3, lines 41-54, placing perforated end of tube 31 into wound);

d) using the proximal end of the proximal segment to create a second opening in the wall of the space or cavity to be drained and advancing the proximal segment completely through the second opening created in the wall, before or after placing the distal end of the drainage device within the space or cavity to be drained through a first opening (col. 3, lines 41-54, needle 15 passed through healthy tissue);

e) allowing the distal end of the second component of the drainage device to remain in place for an extended period of time in order to drain drainage material from the space or cavity into the central lumen of the tubular mesh (col. 4, lines 13-26, drainage device left in wound for sufficient time to drain material, especially while patient would roll, lean or sit on it);

f) allowing the second component to become occluded with drainage material (col. 4, lines 13-26, drainage device left in place; Examiner interprets this time as sufficient to occlude a drain with material); and

Magers discloses the invention substantially as claimed, see above. However, Magers lacks step g) as claimed [claim 50]. Ouriel discloses a step of:

g) withdrawing a tubular mesh proximally from a second component, thereby binding the occluding drainage material within the tubular mesh, and thereby unoccluding the second component (¶ [0048], second catheter assembly 70 retracted into first catheter assembly, and filter 76 trapping fragments). See discussion of claim 1 above regarding rationale and motivation to modify Magers in view of Ouriel.

25. Regarding claims 51-55, 57, 59 and 60, Magers discloses a method where:

[51] the space or cavity is within a human (col. 2, lines 58-68, surgeon operating on patient; Magers suggests operating on a human);

[52] the space or cavity is created by a surgical procedure (col. 3, lines 41-54, draining fluid from surgical wound);

[53] the first opening is a naturally existing opening (col. 3, lines 41-54, surgical wound; Examiner interprets a surgical wound broadly as “naturally existing,” in other words, a surgical wound exists initially, then the surgeon applies a drainage device);

[54] the first opening is a man-made opening (col. 3, lines 41-54, surgical wound);

[55] the first opening is a surgical incision (col. 3, lines 41-54, surgical wound);

[57] further comprising separating the proximal segment of the first component from the intermediate segment after creating the second opening in the wall of the space or cavity (col. 3, lines 41-54, especially lines 50-54, separating needle 15 from tube 13);

[59, 60] where the first opening through which the distal end of the drainage device is placed is closed by suturing or stapling after placing the distal end of the drainage device within the space or cavity (col. 3, lines 55-60, especially line 55, wound completely closed; Examiner notes that suturing and stapling are common surgical techniques for closing wounds);

26. Regarding claim 61, Magers discloses the invention substantially as claimed; see above. Examiner notes that Magers eventually withdraws a second component, since wound drainage catheters do not remain in the body indefinitely. However, Magers lacks a step of removing a tubular mesh as claimed [claim 61]. Ouriel discloses a step of withdrawing a tubular mesh proximally from the second component (¶ [0048], second catheter assembly 70 retracted into first catheter assembly, and withdrawn). Ouriel removes thrombolytic particles from the body after they have been detached from a drainage catheter. See discussion of claim 1 above regarding rationale and motivation to modify Magers in view of Ouriel.

27. Regarding claim 64, Magers in view of Ouriel discloses the invention as substantially claimed; see above. However, Magers and Ouriel are both silent regarding a step of closing a second opening as claimed [claim 64]. Examiner takes Official Notice that closing surgical wounds after surgery is a common step. In other

words, a surgeon will close a wound after removing any implanted devices, to prevent infection or prevent a wound from re-opening. Sutures, staples or surgical glues are commonly used to close small incisions left by implanted drains.

28. Regarding claims 65 and 66, Magers discloses steps of:

[65] attaching the proximal end of the intermediate segment to a suction device after placing the distal end of the drainage device in the space or cavity (col. 3, lines 50-54, attaching tube 13 to bore 33, leading to suction unit 10);

[66] attaching the proximal end of the second component to a suction device (col. 3, lines 50-54, Figs. 1, 2, left and right sides of tube 13 in fluid communication and both attached to suction unit 10).

Magers discloses the invention as substantially claimed; see above. However, Magers lacks a step of withdrawing a tubular mesh as claimed [claim 66]. Examiner cites Ouriel as teaching a step of withdrawing a tubular mesh. See discussion of claim 50 above regarding rationale and motivation to modify Magers in view of Ouriel.

29. Regarding claims 69-71, Magers discloses the invention substantially as claimed, including a step of inserting a drainage device; see above. Magers lacks steps of providing and withdrawing an occlusion removing structure, and Examiner cites Ouriel as teaching these steps; see discussion of claim 50 above. Magers and Ouriel disclose the invention as substantially claimed, but both lack steps of providing and removing a replacement occlusion removing structure as claimed [claims 69-71]. Examiner interprets the repeated steps as a duplication of parts. That is, repeating steps of providing and removing an occlusion removing structure provides the same effect

(removing occlusions) using duplicated parts (the occlusion removing structure of Ouriel). See discussion of claim 46 over Magers, Ouriel and Giesy regarding rationale and motivation to duplicate the providing and withdrawing steps of Magers and Ouriel in order to clean a drain several times.

30. Claims 8, 14, 23, 24, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magers; Paul E. et al. (US 3742952) in view of Ouriel, Kenneth et al. (US 20030097114), further in view of DiResta, Gene R. et al. (US 20030149407).

31. Regarding claims 8, 14 and 23, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks second and third connectors as claimed [claim 8]. DiResta discloses a catheter for reducing interstitial pressure (¶ [0002], [0016], [0033], Fig. 1, apparatus 10), comprising:

a first component intermediate segment (¶ [0033], Fig. 1, connection member 16);

a second component for drainage (¶ [0033], Fig. 1, aspiration probe 12);

[8] where the distal end of the intermediate segment comprises a second connector for joining the intermediate segment to the second component non-integrally (¶ [0038], Fig. 1, first end 36 and seal 38); and

[14] where the second component further comprises a third connector at the proximal end of the second component, where the third connector is configured to mate non-integrally with the second connector on the distal end of the intermediate segment (¶ [0034], Fig. 1, open proximal end 20 connecting to first end 36);

[23] comprising one or more than one structure for securing the drainage device connected to the proximal end of the second component (¶ [0034], Fig. 1, open proximal end 20 connecting to first end 36; Examiner notes that claims 8, 14 and 23 are depend alternately on claim 1, and therefore the connection between end 20 and end 36 are interpreted alternately as second/third connectors or structures for securing);

DiResta connects first and second components selectively, to clean an occluded second component (¶ [0037], [0038], cleaning blocked slit 26 with cleaning obturator 28). One would be motivated to modify Magers in view of Ouriel with the second and third connectors or structures for securing as taught by DiResta to selectively clean a blocked drainage catheter since Magers calls for preventing backwards flow into a wound as discussed for claim 1 above. A second connector allows a surgeon to disconnect first and second components temporarily when a drainage member is blocked, and then reassemble the drainage device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Magers in view of Ouriel as discussed with the second connector as taught by DiResta in order to decouple first and second components selectively when cleaning.

32. Regarding claim 24, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks a loop as claimed [claim 24]. DiResta discloses a connecting structure that is a loop (¶ [0040], Fig. 1, suture ring 44 comprising hole 46). DiResta maintains an implant in place by securing the loop through sutures (¶ [0040]). One would be motivated to modify Magers in view

of Ouriel with the loop as taught by DiResta to hold a drainage device in place, since Magers calls for a drain that continues to function when a patient rolls around or moves (col. 4, lines 13-26, patient rolling, leaning or sitting on implant). A surgical loop of DiResta prevents an implant from detaching from these forces. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Magers in view of Ouriel as discussed with the loop as taught by DiResta in order to maintain an implant in place.

33. Regarding claims 62 and 63, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks a structure for securing the drainage device as claimed [claims 62 and 63]. DiResta discloses a catheter for reducing interstitial pressure (¶ [0002], [0016], [0033], Fig. 1, apparatus 10), comprising:

a first component intermediate segment (¶ [0033], Fig. 1, connection member 16); and

a drainage device or second component (¶ [0033], Fig. 1, aspiration probe 12);

[62] where the drainage device further comprises one or more than one structure for securing the drainage device connected to the proximal end of the second component (¶ [0038], Fig. 1, first end 36 and seal 38); and

[62] where the method further comprises attaching the one or more than one structure to a surface to anchor the drainage device (¶ [0034], Fig. 1, connecting open proximal end 20 to first end 36); and

[63] detaching the one or more than one structure from the surface before withdrawing the second component (¶ [0034], [0038], Fig. 1, required disconnecting between open proximal end 20 and first end 36 when inserting or removing obturator 28). DiResta selectively opens a drainage device for cleaning. One would be motivated to modify Magers in view of Ouriel with the structure for securing and detaching step as taught by DiResta to clean a drainage device since Magers calls for preventing fluid backup as discussed for claim 1 above. See discussion of claim 8 above regarding rationale and motivation to modify Magers and Ouriel in view of DiResta.

34. Claims 21, 22, 40, 44, 46 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magers; Paul E. et al. (US 3742952) in view of Ouriel, Kenneth et al. (US 20030097114), further in view of Giesy; Jerry D. et al. (US 5152749).

35. Regarding claims 21, 22, 40 and 44, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks a third component or introducer as claimed [claims 21, 22 and 44]. Giesy discloses a suprapubic catheter for implanting in the body (col. 2, lines 44-59, col. 5, lines 38-41, Fig. 1, device 10), comprising

a proximal segment that is a trocar (col. 5, lines 46-53, Figs. 1, 2, rigid needle 20);

[21] a third component comprising a proximal end, a distal end, and a hollow tube comprising a wall with an outer surface and an inner surface defining a central lumen (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22); and

[21] where the proximal end of the proximal segment fits snugly into the central lumen of the third component and where the third component is non-integral with the first component (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22 slidably mounting to needle 20);

[22, 40] where the hollow tube of the third component is flexible (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22 conforming to shape of needle 20);

[44] a kit for removing an occlusion from an occluded drain comprising a drainage device according to claim 1, and further comprising an introducer (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22 slidably mounting to needle 20; claims 21 and 44 depend alternately on claim 1, therefore Examiner interprets the flexible sheath alternately as a third component or introducer).

Giesy protects a sharpened trocar before a surgeon is ready to implant a drain (col. 3, lines 1-9, especially lines 7-9, selectively shielding tip), the same application as discussed in Applicant's specification (p. 18, lines 5-9). Additionally, sheath 22 of Giesy dilates tissue (col. 6, lines 18-26). One would be motivated to modify Magers in view of Ouriel with the third component or introducer as taught by Giesy to protect a surgeon from accidental needle sticks, since Magers also has a sharpened trocar.

36. Regarding claim 46, Magers, Ouriel and Giesy disclose the invention substantially as claimed, including an occlusion removing structure (filter 76 of Ouriel) as discussed for claim 1 above. However, Ouriel discloses only a single filter 76. Therefore, Magers, Ouriel and Giesy lack a replacement occlusion removing structure as claimed [claim 46]. Examiner interprets the claimed replacement occlusion removing

structure as a duplication of parts. The MPEP 2144.04(VI)(B) requires an invention made through duplication of parts to have a “new” and “unexpected” result for patentability. The claimed invention lacks these qualities. It is well known in the art that a filter that captures thrombosed particles and become clogged. Providing extra filters to replace a clogged filter keeps a drainage lumen clear and allows for multiple cleanings of the same lumen. In other words, replacement filters allow a drain to be cleaned several times while it is implanted in the body, to keep the lumen clear while it is implanted. Therefore, the duplication of a filter or occlusion removing structure does not provide a “new” and “unexpected” result.

37. Regarding claim 58, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks a third component as claimed [claim 58]. Giesy discloses a drainage device comprising:

a third component comprising a proximal end, a distal end, and a hollow tube comprising a wall with an outer surface and an inner surface defining a central lumen (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22); and

where the proximal end of the proximal segment fits snugly into the central lumen of the third component, where the third component is non-integral with the first component (col. 5, lines 54-60, Figs. 1, 2, flexible sheath 22 slidably mounting to needle 20); and

where the method further comprises removing the third component by axially sliding the third component proximally relative to the first component (col. 6, lines 17-26, sheath 22 dismounted from device 10). Regarding a limitation of sliding a third

component proximally, Giesy reverses 'proximal' and 'distal' directions as defined in Applicant's specification. However, Examiner notes that sheath 22 needs to move towards the end of a needle (a proximal direction) when removed since handle 12 blocks distal movement. Additionally, Giesy suggests removing a sheath, since several sheaths 22 may be provided in order to dilate an opening to a needed degree (col. 6, lines 17-26, especially lines 18-22). Here, Giesy prevents accidental injury from a sharp trocar, and dilates a surgical opening to a selected degree. One would be motivated to modify Magers in view of Ouriel with the third component of Giesy since Magers also provides a sharpened trocar that needs to be protected before a surgeon deploys it.

38. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magers; Paul E. et al. (US 3742952) in view of Ouriel, Kenneth et al. (US 20030097114) in view of Giesy; Jerry D. et al. (US 5152749), further in view of Hart; Charles C. et al. (US 5868708)

39. Regarding claim 56, Magers and Ouriel disclose the invention substantially as claimed, including a sliding step of Ouriel (¶ [0048], second catheter assembly 70 withdrawn from blood vessel). Regarding the limitation of sliding a tubular mesh proximally, Ouriel slides filter 76 out of a blood vessel (¶ [0048]). In other words, Examiner interprets the direction exiting a blood vessel as the proximal direction. Magers, Ouriel and Giesy disclose the invention as substantially claimed; see above. However, none of Magers, Ouriel or Giesy disclose a rotating step.

Hart discloses a balloon catheter used for dislodging blockage (col. 2, lines 9-15, cols. 5-6, lines 65-9, Fig. 2, surgical device 10 for clearing vascular conduit 2), and a method of using comprising a rotating step (col. 5, lines 8-16). One would have been motivated to modify Magers, Ouriel and Giesy with the rotating step of Hart, since Ouriel suggests a need to dissolve a thrombus before withdrawing a filter (¶ [0005]). Rotating the tubular mesh in contact with a thrombosis further removes particles. Additionally, first catheter 20 and second catheter 70 of Ouriel are movable relative to each other. Here, Hart demonstrates that a rotating step further removes thrombosis from a tubular lumen when using a wire mesh element (col. 7, lines 9-24, especially lines 17-19).

40. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magers; Paul E. et al. (US 3742952) in view of Ouriel, Kenneth et al. (US 20030097114), further in view of Jacobs, Joseph B. et al. (US 20030045862)

41. Regarding claim 67, Magers in view of Ouriel discloses the invention substantially as claimed, see above. However, Magers in view of Ouriel lacks a cutting step as claimed [claim 67]. Jacobs discloses a sinus cannula (¶ [0021], Fig. 1, cannula 10) comprising a flexible tube (¶ [0021], [0022], Fig. 1, tube 12). Jacobs trims a flexible tube to size before implanting it (¶ [0022], tube 12 trimmed at proximal end 14 before implanting). Jacobs sizes a drainage tube to a patient, based on individual needs. One would be motivated to modify Magers in view of Ouriel with the cutting step of Jacobs to tailor individual patients since both Magers and Jacobs drain cavities with flexible tubes.

Cutting tube 13 of Magers before inserting it into a wound allows the drain to fit securely within a wound without excess portions extending from the wound.

42. Regarding claim 68, Magers, Ouriel and Jacobs disclose the invention substantially as claimed, including the cutting step of Jacobs; see above. However, Magers, Ouriel and Jacobs are silent whether a tubular mesh retracts when cut as claimed [claim 68]. Ouriel discloses that filter 76 comprises a springy, resilient material that returns to its original shape (¶ [0039], coil members 122, 124 made of Nitinol). Therefore, Examiner interprets the coil members 122, 124 of Ouriel as capable of retracting when cut. One would be motivated to modify Magers in view of Ouriel with the retracting material of Ouriel to provide a compact device, since filter basket 76 is eventually retracted within a first catheter assembly 20.

Double Patenting

43. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

44. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

45. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

46. Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/031,563 published as Deutsch '373, Harvey L. (US 20050154373). Although the conflicting claims are not identical, they are not patentably distinct from each other because Deutsch '373 claims both means for drainage and means for removing an occlusion of instant claim 43 in claim 1. Regarding the limitation of "a space or cavity defined by a wall," Deutsch '373 claims a method that places the drainage device into an area to be drained (claim 2). Examiner notes that enclosed spaces or cavities are routinely drained with surgical devices. That is, adding the limitation of a "space or cavity" is not sufficient to differentiate instant claim 43 from claims 1 and 2 of Deutsch '373.

47. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

48. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Hillstead R A US 4921484
- Mattox D E et al. US 5628733
- Righetti R et al. US 6605068
- Aboytes M et al. US 20040073243
- Sheridan; David S. US 3595241
- Brugarolas; Antonio et al. US 3753439
- Comoy E et al. US 6792305
- Beck; Walter et al. US 4661093
- Loseff; Herbert S. US 3908664
- Marcus; William Y. US 5336177
- Mcelvenny Robert T et al. US 3115138
- Guenther; Rolf W. et al. US 5102415

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

51. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 August 2009